The University of Texas at Austin

Office of Research Support & Compliance
P.O. Box 7426, Campus Code A3200
Austin, Texas 78713
T: 512-471-8871 F: 512-471-8873
www.research.utexas.edu/ors

IRB Reliance Guidance

Office of Research Support & Compliance, The University of Texas at Austin

What is IRB Reliance?

IRB Reliance is when an IRB agrees to rely on another IRB for the review and approval of a non-exempt research project. IRB Reliance can be established between institutions or between an institution and an independent IRB, such as Western IRB or the NCI Central IRB. A reliance arrangement is particularly useful when multiple study sites are following the same study protocol or procedures. Reliance arrangements can also be useful when some of the study sites or partners do not have their own IRB.

Reliance agreements may be put in place when:

- UT Austin has agreed to be a reviewing IRB for one or more other institutions / organizations
- UT Austin has agreed to rely on the IRB of another institution or an independent IRB

Anytime a researcher affiliated with UT Austin is engaged in the conduct of human subject research and wishes to rely on an IRB other than the UT Austin IRB, the Office of Research Support and Compliance must agree to the arrangement, and UT Austin must sign a reliance agreement with the reviewing IRB. An individual is considered engaged in the conduct of human subjects research when carrying out activities such as consenting subjects, collecting data, or analyzing identifiable data. Please note, UT IRB will not enter into an authorization agreement for research determined to be exempt.

How is IRB Reliance Documented?

In order to establish a reliance arrangement, the participating institutions or organizations must enter into a reliance agreement to document the arrangement. This agreement may be called a reliance agreement or an authorization agreement. These agreements are most often study specific; however, some master agreements exist to document the reliance arrangement between institutions for any study. Reliance agreements must be signed by an authorized institutional official since the agreement is between institutions and not between investigators.

Has UT Austin signed any master reliance agreements?

UT Austin has signed the following master agreement(s). We will be adding additional agreements with commercial IRBs for review of industry sponsored research.

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- **SMART IRB**, which is an IRB reliance agreement signed by more than 400 institutions and independent IRBs. Check the SMART IRB website to determine if an entity has signed the SMART IRB agreement.

Until specific agreements are signed with the major independent IRBs, UT is able to utilize the SMART IRB agreement to facilitate reliance with these IRBs.

How do I request a reliance arrangement if I want UT Austin to serve as the reviewing IRB (IRB of Record)?

First, you should contact the Office of Research Support and Compliance at irb@austin.utexas.edu to determine that the UT IRB is willing to serve as the IRB of Record (reviewing IRB) for other participating sites. Until further notice, the UT Austin IRB will consider serving as the IRB of Record when the study involves no more than 4 sites. If a study will involve more than 4 sites, please discuss options with the RSC Assistant Director for the IRB Program or the Assistant Vice President for Research Support and Compliance.

When you are ready to submit your study for review, you should submit your study as usual. You will make the request in Section 4a of the IRB Proposal Template that asks for information about study locations. Each relying site must complete the form "Site Specific Application for Relying on the UT IRB." This application and any supporting documentation should be submitted to the UT IRB by the UT PI.

UT PI directed study with relying sites: When study procedures will occur at multiple sites and all study procedures are being directed by the UT PI (i.e., no site PIs), requests for reliance from participating sites can be made at the time of the initial submission or via amendments.

Multicenter study: If the study is a multicenter study where all sites have their own PI and will follow a standardized protocol, your initial submission should not identify any relying sites. The UT IRB will approve the protocol and template forms, such as informed consent. After the initial submission is approved, you should submit an amendment to add non-UT Austin sites. The reason for adding sites via amendment after the initial protocol is approved is so that template forms can be approved before relying sites submit these forms with institution specific information for IRB review. Otherwise, if the UT IRB requires changes to any of the template forms, each site would need to make changes to the documents they had submitted for review.

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What information needs to be provided by a relying site when the UT Austin IRB is serving as the reviewing IRB?

Relying sites must provide:

- Site specific application for relying on the UT IRB
- Any study documents that have been customized for the site (i.e., informed consent form)
- Communication plan

How do I request a reliance arrangement if I want UT to rely on another IRB?

First, contact irb@austin.utexas.edu before you proceed with any submission to ensure that UT is amenable to relying on the other IRB. Taking this step can save you time in the long run.

Once you have determined that UT is willing to rely on the external IRB, you must submit an abbreviated submission in IRBAccess to formally request the reliance. When submitting an application in IRBAccess, choose "Request to Rely on an External IRB" on Step 1, Question 2 of the online application.

Instead of submitting the standard Protocol Template, you should submit the following documents along with your electronic application:

- Request to Rely on an External IRB form
- PI's curriculum vitae
- Study protocol or IRB application approved by the reviewing IRB, if applicable
- Informed consent(s) and HIPAA authorizations that will be used at UT Austin
- Approval letter for the study from the external IRB, if already approved
- Any local context form(s) required by the external IRB
- Verification of all applicable institutional approvals, such as IBC approval

The submission will be reviewed for compliance with institutional requirements and other typical requirements of an external IRB including:

- Determining the PI is qualified and has appropriate credentials and privileges to conduct the research
- Verifying that all research personnel have completed CITI human subjects training and GCP training, if applicable

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- Verifying that a COI review has been completed, and sharing any COI management plan with the external IRB
- Conducting HIPAA approvals for waiver of authorization, if applicable
- Confirming that IBC approval is in place, as needed

UT will correspond with the PI and/or the external IRB to finalize the reliance arrangement and document the agreement.

How do I know if UT needs to enter into a reliance agreement with the reviewing IRB?

Whenever the research personnel, including PI and all study staff, will be representing themselves as UT affiliated individuals during the conduct of the study, UT needs to enter into a reliance agreement with the reviewing IRB.

Compliance Review Fee for Industry Sponsored Research

UT charges a compliance review fee of $1500 to conduct this internal review for industry sponsored studies. There is no charge for this review for non-industry sponsored research. Funds to pay this fee should be built into industry sponsored study budgets. Once the Research Support and Compliance review is complete, RSC will invoice the department for the funds.

After my study is approved by an external IRB, what are my responsibilities?

Responsibilities with the Reviewing (External IRB)

When your study is approved by an external IRB, you are responsible for following all of the policies of the Reviewing IRB. The study PI and all research personnel should be familiar with the policies of the Reviewing IRB. These responsibilities may be outlined in the reliance agreement or the approval letter, but typically will include:

- Adhering to the study procedures approved by the reviewing IRB
- Submitting any changes for approval prior to implementation (amendments) including changes in study personnel
- Reporting all unanticipated problems and noncompliance within deadlines established by the reviewing IRB
- Reporting any changes in financial relationships that may be perceived as a COI
- Cooperating with any post approval monitoring requests

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Responsibilities with the UT IRB

Even though your study is approved by an external IRB, you still have some responsibilities with the UT IRB. These include:

- Submit the following as amendments to your UT submission:
  - PI and personnel changes to UT for approval prior to submitting to the reviewing IRB [required because most reliance agreements require UT to verify personnel qualifications and training]
  - Addition of drugs or devices
  - Change in research funding
- Submit a report on your UT submission when:
  - An Unanticipated Problem occurs at the UT site (see the UT IRB Policies and Procedures Manual Section 9: Reporting Unanticipated Problems)
  - The reviewing IRB determined that an Unanticipated Problem occurred at the UT site
  - The reviewing IRB determined that Noncompliance occurred at the UT site

  Complete an annual progress check-in notifying the UT IRB about the status of the study (an automatic email notification will be sent to the UT PI and designated study members in IRBAccess with a link to the check-in form).
- Close the study with the UT IRB when the reviewing IRB closes the UT Austin site

What should I do if my grant proposal requires a plan for Single IRB Review, or I am asked to collaborate on a grant that will propose Single IRB Review?

Effective January 25, 2018, the NIH has mandated that all domestic sites participating in a non-exempt, multi-site research study (where activities outlined in a single protocol are carried out at multiple institutions) use a single IRB (sIRB).

Effective January 20, 2020, the Common Rule requires a sIRB for all domestic sites participating in federally funded, non-exempt, cooperative research.

It is important to verify with the ORSC any plans for use of a single IRB before a grant proposal is submitted. If you are preparing a grant proposing that the UT IRB serve as the reviewing IRB, it is particularly important to contact irb@austin.utexas.edu at least 2 weeks before your proposal is due to ensure the UT IRB is willing to serve. Similarly, if the grant will require that UT rely on an external IRB, it is

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important to contact irb@austin.utexas.edu in plenty of time to receive a response prior to the grant deadline.

Budget Considerations: IRBs may charge for the review of external site submissions, even on federally funded projects. Thus, it is important to consider potential IRB charges in grant budgets. When another IRB will serve as the reviewing IRB, it will also be important to determine whether that IRB will charge a fee for initial and ongoing reviews for the UT site, and account for these charges in your budget.

When the UT IRB serves as the reviewing IRB for a federally funded multisite study for which single IRB review is required, the following charges will be assessed. The UT PI's department is responsible for paying the charges and recouping the costs from participating sites.

Activity	Cost per Site
Negotiate Reliance Agreement - Smart IRB or Master Agreement	$120
Negotiate Agreement - Other	$320
Initial Site Approval	$300
Site Modification or Closure	$900 / academic year*
Unanticipated Problem – Site	$445
Full Board Study	
Negotiate Reliance Agreement - Smart IRB or Master Agreement	$120
Negotiate Agreement - Other	$320
Initial Site Approval (reviewed as an expedited amendment)	$300

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Full Board Modification	$370
Expedited Modification / Site Closure	$900 / academic year*
Full Board Continuing Review	$445
Unanticipated Problem	$445

*The UT IRB will assess an annual charge of $900 per site to cover costs associated with approving site amendments. The annual fee remains the same regardless of the number of amendments.

Fees will be assessed starting on September 1, 2020 for all federally funded multisite studies initially awarded after January 20, 2020.